JUN 30 2008

K080379

Summary of Safety and Effectiveness

Submitter Name and Address:	Micrus Endovascular Corp. 821 Fox Lane San Jose, CA 95131
Contact Name:	Patrick Lee Phone: 408-433-1428 Fax: 408-433-1585 Email: plee@micruscorp.com
Preparation Date:	February 22, 2008
Device Name and Classification:	Micrus Microcoil System Common Name: Occlusion Coil Trade Name: Micrus "**Deltapaq 10 Stretch-Resistant**" Microcoil System, Catalog # DFS Classification Name: Device, Neurovascular Embolization Regulatory Class II
Predicate Devices:	Micrus Stretch-Resistant Microcoil, 510(k) no. K022420
Device Description:	The Micrus Deltapaq 10 Stretch-Resistant Microcoil Systems consists of an embolic coil ("Microcoil") attached to a Device Positioning Unit (DPU) (single use, sterile)
Device Intended Use	The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

Comparison to Predicate Device:

The Micrus Deltapaq 10 Stretch-Resistant Microcoil System has shown substantial equivalence to the Micrus Stretch-Resistant Microcoil System in terms of intended use, design, material of construction, implant dimensions including wire dimensions, coil dimensions, coil pitch, and coil stiffness. The Deltapaq 10 Stretch-Resistant microcoils use the same method and material of construction, packaging, and sterilization method as its predicate. The modification has not altered the fundamental technology of the sponsor's predicate device

Conclusion:

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Micrus Endovascular Corporation, it is concluded that the Micrus Deltapaq 10 Stretch-Resistant Microcoil System is substantially equivalent to the predicate device in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2008

Micrus Endovascular Corporation
% Mr. Patrick Lee
Regulatory Affairs Specialist
821 Fox Lane
San Jose, California 95131

Re: K080379
Trade/Device Name: Micrus Microcoil Delivery Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: April 2, 2008
Received: June 4, 2008

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080379

Indications for Use

510(k) Number (if known): _____

Device Name: Micrus Microcoil Delivery Systems

Indications For Use:

The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080379